



**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

TD

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/050,991	03/31/98	GETZENBERG	R 76333/150

FOLEY AND LARDNER
3000 K STREET, N.W.
SUITE 500
WASHINGTON DC 20007-8696

HM12/1201

EXAMINER

EFPS, J

ART UNIT	PAPER NUMBER
----------	--------------

1635

DATE MAILED:

12/01/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/050,991

Applicant(s)
Getzenberg

Examiner
Janet Epps

Group Art Unit
1635



☒ Responsive to communication(s) filed on Oct 19, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1035 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-47 is/are pending in the applicat

Of the above, claim(s) 4-15, 18-20, 22-39, and 44-47 is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-3, 16, 17, 21, and 40-43 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 3-4, 6

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Art Unit: 1635

DETAILED ACTION

Election/Restriction

1. Applicants elected with traverse, claims 1-3, 16, 17, 21, and 40-43. Claims 4-15, 18-20, 22-23, 27-31, 34-39, 44-47, 24-29, and 32-34, have been withdrawn as being drawn to a non-elected invention. Applicants traversed on the basis that claims drawn to method of use claims “corresponding in scope to any eventually allowed product may be rejoined pursuant to the *Ochiai/Brouwer* guidelines.” The separation of claims into groups was not based upon the separation of a product from methods of use claims. Restriction of claims into Groups I-III, drawn to proteins, polynucleotides, and antibodies, was deemed proper because these inventions are distinct because they have acquired a separate status in the art because of their recognized divergent subject matter. Furthermore, the inventions are distinct because they are physically and functionally distinct chemical entities, and because the protein, polynucleotide, and antibodies can be used in materially different processes from each other, restriction for examination purposes as indicated is proper.

2. Applicant's election of Invention I in Paper No. # 8/a is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Art Unit: 1635

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 3, 16-17, 21, and 40-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Coffey et al. (PTO-1449)

Coffey et al. disclose nuclear matrix proteins (NMPs) which are characterized by a defined expression in tissue. These NMPs are useful in diagnosing and monitoring the stage of malignancy of a cell and treating cell proliferative disorders. Specifically, Coffey et al. disclose, PC-1 (MW 56 kD), an NMP that is seen in human prostate cancer tissue, malignant kidney and bladder cancer specimens, but not detected in normal prostate, kidney, or bladder tissue. (p. 47, lines 20-25). The method of diagnosing the stage of malignancy of a cell can be accomplished by using antibodies targeting the NMP, or a nucleic acid probe (p. 53, all). In addition, Coffey et al. teach methods of identifying factors which would potentially modify the activity of an NMP, for example monoclonal antibodies and antisense nucleic acids (p. 36).

Coffey et al. teach each and every aspect of the instant invention thereby anticipating applicant's claimed invention.

Art Unit: 1635

5. Claims 1-2, 16-17, and 21 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Miyanaga et al.

Miyanaga et al. disclose a Nuclear Matrix Protein (NMP) that is a 100 kD protein that is released in soluble form from cells undergoing cell death. This protein was used as a urine marker for transitional cell carcinoma. Miyanaga et al. further teach that their disclosed NMP of 100kD maybe useful in the screening of bladder cancer patients, and for continuous follow-up screening after surgery (p. 457, abstract).

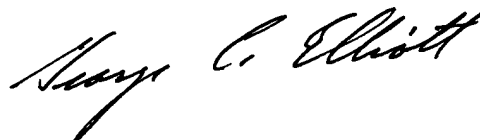
Miyanaga et al. teach each and every aspect of the instant invention thereby anticipating applicants' claimed invention.

Art Unit: 1635

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps whose telephone number is (703) 308-8883. The examiner can normally be reached on Monday through Friday from 8:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, George Elliott, can be reached at (703) 308-4003. The fax number for this group is (703) 305-7939.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



George C. Elliott, Ph.D.
Supervisory Patent Examiner
Technology Center 1600

Janet L. Epps, Ph.D.

November 29, 1999